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No. 98-1768

In the Supreme Court of the United States

BUCKMAN COMPANY, PETITIONER

v.

PLAINTIFFS' LEGAL COMMITTEE

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

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This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States.

STATEMENT

Respondents claim that they suffered injuries from the implantation of orthopedic bone screws into the pedicles of their spines. They allege that petitioner fraudulently obtained regulatory clearance for the manufacturer to market the pedicle screws by misrepresenting to the Food and Drug Administration (FDA) that the screws were "intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones," even though, respondents contend, the screws were designed and sold "exclusively for use in the spine." Pet. App. 8a. The question presented is whether, as petitioner contends, that claim of "fraud on the FDA" is preempted by federal law.

1. a. The Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, as amended, empowers the FDA to regulate a wide variety of products. The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, supplemented the FDCA's original provisions by creat-

ing a federal program to enhance "the safety and effectiveness of medical devices intended for human use" (90 Stat. 539 (Preamble)). See *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475-477 (1996). The MDA authorizes the FDA to undertake specified review, clearance, approval, and other regulatory activities with respect to medical "devices," which include instruments, implants, and similar articles that are intended for use in the treatment, mitigation or prevention of disease or to affect the structure or function of the body. See 21 U.S.C. 321(h) (defining "device"), 360c-360*l* (1994 & Supp. IV 1998) (regulatory program).

The MDA directs the FDA to group medical devices into three classes, based on the degree of regulation it concludes is necessary to provide reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a) (1994 & Supp. IV 1998); see *Medtronic*, 518 U.S. at 475-476. Class III devices are those that present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C). The makers of Class III devices are subject to a variety of controls and to the FDA's statutory "premarket approval" (PMA) process. 21 U.S.C. 360c(a)(1)(C) and 360e(a). To obtain a PMA, the manufacturer must submit detailed information to provide the FDA with reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a) and (c); 21 U.S.C. 360e(d) (Supp. IV 1998); 21 C.F.R. Pt. 814.[1]

Class III devices that were on the market before the MDA's enactment, however, may be marketed without FDA review until the FDA, by rulemaking, requires the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In the interest of

[1] Class I devices are those that present no unreasonable risk of illness or injury and are subject to only minimal regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Devices that are potentially harmful are Class II devices; they may be marketed without advance approval, but manufacturers must comply with federal standards known as "special controls." 21 U.S.C. 360c(a)(1)(B). See *Medtronic*, 518 U.S. at 476-477.

fairness and to prevent the "grandfathered" manufacturers from monopolizing the market, the FDA also permits other manufacturers to distribute similar devices by showing (through a premarket notification process) that they are "substantially equivalent" to the grandfathered devices. 21 U.S.C. 360e(b)(1)(B). That procedure is known as the "Section 510(k) process," referring to the FDCA section codified at 21 U.S.C. 360(k). See *Medtronic*, 518 U.S. at 478-479.

When respondents were allegedly injured by the pedicle screw spinal system at issue in this case, the FDA had not yet classified that device. The FDA subsequently classified and reclassified pedicle screw spinal systems intended for certain uses as Class II devices, subject to special controls. See 63 Fed. Reg. 40,025 (1998); 21 C.F.R. 888.3070(a); pp. 13-14, *infra*. Pedicle screw spinal systems intended for all other uses are Class III devices. See 21 C.F.R. 888.3070(b).

b. The MDA contains an express preemption provision, 21 U.S.C. 360k(a), which provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

See also 21 U.S.C. 360k(b) (permitting FDA to grant exemptions from preemption).

This Court addressed Section 360k's preemptive effect in *Medtronic*. There, the plaintiffs sought damages for injuries caused by a pacemaker, which, they alleged, was defectively

designed, built, and manufactured. The FDA had cleared the pacemaker, a Class III medical device, for distribution under Section 510(k) on the ground that it was "substantially equivalent" to a pre-MDA device. Medtronic, the manufacturer, contended that Section 360k preempted plaintiffs' tort claims. This Court disagreed.

The Court first held that Medtronic's compliance with the Section 510(k) process did not impose any "requirements" on the device—and thus did not preempt plaintiffs' design defect claims—because the FDA's clearance did not "require" the pacemaker "to take any particular form for any particular reason." 518 U.S. at 493; accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part) (Section 510(k) process "places no 'requirements' on a device" and therefore does not preempt design defect claims). The Court next held that Section 360k did not preempt state-law claims in which the duty of care was based on FDA requirements, because those claims did not subject Medtronic to state-law requirements that were "different from, or in addition to," the federal requirements. *Id.* at 495. The Court noted that the FDA's interpretive regulations "expressly support the conclusion that § 360k 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the Act.'" *Id.* at 496-497 (quoting 21 C.F.R. 808.1(d)(2) (1995)).

Finally, the Court held that Section 360k did not preempt the plaintiffs' claims based on negligent manufacturing and labeling. 518 U.S. at 497-502. The Court recognized that FDA regulations set out general "requirements" for manufacturing and labeling medical devices. *Id.* at 497. It concluded, however, that Section 360k does not mandate preemption of state-law requirements with respect to a device unless, as suggested in FDA regulations interpreting Section 360k, the FDA has adopted specific counterpart regulations or other specific substantive requirements applicable to the particular device. *Id.* at 498-500 (citing 21 C.F.R.

808.1(d) (1995)). The Court therefore concluded that the "entirely generic" federal manufacturing and labeling requirements did not provide a basis for preemption of the general state common law duties at issue in that case. *Id.* at 501; see also *id.* at 505- 507 (Breyer, J., concurring in part and concurring in judgment). In his separate opinion, Justice Breyer, agreeing with Justice O'Connor's opinion for four Justices (see *id.* at 509-512), concluded that, ordinarily, insofar as the MDA preempts a state requirement embodied in a statute or regulation, it also preempts a similar state requirement that takes the form of a standard of care imposed by state tort law, *id.* at 503-505; but he concurred in the Court's holding that the federal manufacturing and labeling requirements were not sufficiently "specific" to trigger preemption, *id.* at 505-508.[2]

2. Petitioner, a regulatory consultant, was retained by the AcroMed Corporation, a medical device manufacturer, to act as its liaison to the FDA. In September 1984, petitioner, on behalf of AcroMed, made a submission for Section 510(k) marketing clearance for an orthopedic bone screw device known as the Variable Screw Placement (VSP) Spinal Plate Fixation System. Petitioner's submission stated that Acro-

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[2] As we informed the Court in a response to the Court's invitation in a subsequent case presenting preemption issues under the MDA, in 1997 the FDA proposed an interpretive rule to give further guidance on the meaning of Section 360k. See U.S. Amicus Br. 19-20, *Smiths Indus. Med. Sys., Inc.* v. *Kernats*, cert. denied, 522 U.S. 1044 (1998) (No. 96-1405). That rule would have expressly construed Section 360k, consistent with the opinions in *Medtronic*, to preempt a common law duty only when (1) the FDA has imposed, by regulation or order, a specific substantive requirement applicable to a particular medical device, and (2) state common law imposes a substantive requirement applicable to the same medical device that is different from, or in addition to, the FDA's counterpart requirement. 96-1405 U.S. Br. App. 9a-15a, 17a-18a. After further consideration, the FDA withdrew that proposed rule. See 63 Fed. Reg. at 39,789. That withdrawal has no bearing on the preemption question presented here, and the interpretation of Section 360k in this brief is consistent with the interpretation in the proposed rule and in our brief in *Smiths Industries*.

Med intended to market the device for use in spinal surgery. The FDA denied the request, finding that the VSP device was a Class III device and was not substantially equivalent to any predicate device marketed before the MDA's enactment. In September 1985, petitioner filed a second submission for marketing clearance, again stating that the device was intended for use in spinal surgery. The FDA again denied the submission on the ground that the device was not substantially equivalent to any predicate device and that it posed potential risks not exhibited by other spinal-fixation systems. Pet. App. 4a-5a.

In December 1985, petitioner and AcroMed made a different attempt to obtain marketing clearance through the Section 510(k) process. They split the VSP device into its two component parts, which they called "nested bone plates" and "cancellous bone screws," and they filed separate Section 510(k) submissions for each component. Those submissions stated that the devices were intended to be used in long bones of the arms and legs. After reviewing the submissions, an FDA official contacted petitioner for additional information about the intended use of the device. Petitioner responded that "[t]he proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates [which were marketed before the MDA's enactment] . . . [and] are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis)." C.A. App. A58. In February 1986, the FDA granted marketing clearance for AcroMed's bone plates and screws for this stated purpose. Pet. App. 5a.

3. a. Respondents are some of the more than 5000 plaintiffs who filed suits alleging that they were injured when their doctors inserted the assembled VSP device into their spines. More than 2300 individual suits were brought against multiple defendants, and those suits were consolidated for pre-trial proceedings in the Eastern District of Pennsylvania pursuant to the multi-district litigation statute, 28 U.S.C. 1407 (1994 & Supp. IV 1998). Pet. App. 1a; Pet. 6.

The only count against petitioner is one that respondents call "fraud on the FDA." Pet. App. 5a. That count asserts that petitioner "intentionally and falsely" told the FDA that the AcroMed bone plates and screws were intended for use in fractures of long bones, when, in reality, the "sole intended use of these components was as an assembled [VSP] spinal plate/pedicle screw fixation system." C.A. App. A57, A58. Respondents allege that AcroMed designed the devices to be used exclusively in the spine and that petitioner "sought approval of [the] VSP plates and screws for use in the long bones simply as a pretext in order to market the device for its true intended use in the spine." *Id.* at A58. Respondents further allege that the FDA did not know that the bone plates and screws "were intended by AcroMed to be used as pedicle screw fixation devices," and that if petitioner had not made false statements about their intended use, the FDA would not have cleared the devices for marketing, the devices would not have been sold, and respondents thus would not have been harmed by them. *Id.* at A63.

The district court initially dismissed the "fraud on the FDA" claims on the ground that they were preempted by the MDA. Pet. App. 53a. Relying on the Third Circuit's decision in *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329, cert. denied, 516 U.S. 815 (1995), the district court reasoned that Section 360k "does not permit courts to 'perform the same function initially entrusted to the FDA,'" Pet. App. 49a, and that the FDA is in the "best position" to decide whether a manufacturer "withheld material information from the agency and, if so, [to determine] the appropriate sanction." *Id.* at 50a (quoting *Reeves* v. *AcroMed Corp.*, 44 F.3d 300, 306 (5th Cir.), cert. denied, 515 U.S. 1104 (1995)).

After this Court decided *Medtronic*, respondents asked the district court to reinstate their "fraud on the FDA" claims. Pet. App. 7a. Although the court indicated that this

Court's decision in *Medtronic* foreclosed a finding of express preemption under Section 360k, *id.* at 40a, it nevertheless dismissed respondents' claims on the grounds that they improperly assert a private right of action for violation of the MDA and that the target of the alleged fraud was the FDA, not respondents. *Id.* at 36a-40a. In the alternative, the court dismissed the claims because "the alleged fraud * * * cannot be said to have been a proximate cause of [respondents'] alleged injuries." *Id.* at 41a.

b. A divided panel of the court of appeals reversed. Pet. App. 1a-32a. The court held that Section 360k does not expressly preempt the claims, because there is neither a federal "requirement" "applicable to the device" nor a state "requirement" "with respect to" that device. *Id.* at 13a. Moreover, the court reasoned, the "state common law relied upon [by respondents] does not impose any obligation on [petitioner] inconsistent with federal law," because it is a crime to make a false statement to a federal agency, see 18 U.S.C. 1001 (1994 & Supp. IV 1998), and because FDA regulations require those who seek FDA clearance of devices under Section 510(k) to vouch for the truthfulness and accuracy of their submissions. Pet. App. 13a; see note 5, *infra*.

The court of appeals also rejected the district court's conclusion that the "fraud on the FDA" claims constitute an impermissible attempt to obtain a private right of action for violations of the MDA. Pet. App. 14a-17a. Although the court of appeals itself had relied on similar reasoning in *Michael*, the court found such reasoning inconsistent with this Court's intervening decision in *Medtronic*. *Id.* at 16a. The court therefore disagreed with *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998), a post-*Medtronic* decision in which the Seventh Circuit had followed *Michael* and held that a "fraud on the FDA" tort claim was preempted. Pet. App. 17a n.5.

Finally, the court of appeals reversed the district court's decision to dismiss the claims for the additional reason that

they fail to allege a sufficient causal connection between the asserted fraud and respondents' injuries. Pet. App. 19a-21a. Because neither the parties nor the district court had analyzed the choice-of-law issues raised by the complaint or discussed the law of any particular jurisdiction that would govern the causation element of such a claim, the court of appeals found it impossible to determine whether respondents "have or have not alleged a legally sufficient causal nexus." *Id.* at 21a.

Judge Cowen dissented. Pet. App. 25a-32a. He expressed concern that "recognizing a state cause of action for violations of FDA regulations will greatly distort the penalty scheme established by the statute," because the "penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." *Id.* at 28a.[3]

DISCUSSION

As petitioner correctly contends, the decision below squarely presents at least one issue that has divided the lower courts: whether federal law preempts a state-law cause of action based on a defendant's alleged fraud on the FDA during the regulatory process for marketing clearance applicable to certain medical devices. That issue is important, and this Court should grant certiorari to resolve it.

1. On the merits, we agree with petitioner that respondents' "fraud on the FDA" claim is foreclosed by federal law, but we disagree on why that is so.

a. Contrary to petitioner's contention (Pet. 26-27), the court of appeals was correct in holding that the claim is not expressly preempted by Section 360k. As a general matter,

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[3] The Third Circuit returned to this case in *In re Orthopedic Bone Screw Prods. Liability Litigation*, 193 F.3d 781 (1999), which involved issues arising under certain of plaintiffs' other claims against a variety of defendants. That decision has no bearing on this petition.

a defendant claiming preemption under Section 360k must show, at a minimum, that the application of state law would impose obligations in addition to or different from "specific counterpart regulations" or a federal requirement that is "specific" to a "particular device." *Medtronic*, 518 U.S. at 500 (internal quotation marks omitted); accord *id.* at 506-507 (opinion of Breyer, J.).

Petitioner has identified no such specific federal requirement applicable here. It contends instead that respondents' claim is preempted because it "would threaten to impose liability for failing to disclose in the 510(k) process information that the FDA itself does not require." Pet. Reply Br. 10. But the federal requirement that petitioner argues would be impermissibly supplemented by respondents' state law theory of liability—the requirement that the person making a Section 510(k) submission identify the device's "intended use"—applies to such devices generally; it does not impose a requirement specifically with respect to the VSP device that is the subject of these consolidated cases. See 21 C.F.R. 807.87(e) (1985 & 1999). Compare *Medtronic*, 518 U.S. at 501; *id.* at 506-507 (opinion of Breyer, J.). For that reason, even if (as petitioner contends) respondents' claim depends upon the existence of a state-law duty to provide the FDA with information about intended or "off-label" uses in addition to the information that federal law requires to be disclosed, that claim would not be expressly preempted, because the federal duty of disclosure is insufficiently device-specific to trigger preemption under Section 360k.[4]

[4] Petitioner argues that this case implicates a conflict concerning a separate issue: whether *Medtronic* exempts from express preemption *all* state requirements that are imposed through state tort law of general applicability. See Pet. 19-25. As we explained in our brief in *Smiths Industries* (at 17-18, 19), it is our view that Section 360k does preempt a specific duty of care that is made applicable to a device through a State's common law of torts if that requirement is different from, or in addition to, a specific requirement imposed by the FDA. See *Medtronic*, 518 U.S. at 503-505 (opinion of Breyer, J.); *id.* at 509-512 (O'Connor, J., concurring in part and dissenting in part). See note 2, *supra*. Although we agree that the lower courts are divided on that issue, this case would likely prove to be an inappropriate vehicle for trying to resolve it. The cases underlying that conflict generally involve ordinary product defect claims. As discussed in the text, Section 360k is inapplicable here for reasons independent of whether the application of state tort law is insufficiently specific to be preempted by that provision, and this Court would therefore probably find it unnecessary to resolve the latter issue. As we discuss below, however, this case *does* implicate a separate conflict concerning whether federal law preempts state-law claims of fraud on a federal agency, and certiorari would be appropriate to resolve *that* issue.

In any event, even if the general duty to provide truthful information to the FDA about a product's "intended use" *were* device-specific enough to preempt state-law duties to provide additional information, respondents' claim still might not fall within the scope of Section 360k, because, on the present record, it is not clear that the asserted state common law duty on which respondents rely would, as applied here, be "different from, or in addition to," that federal duty. See *Medtronic*, 518 U.S. at 495; see also *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Petitioner argues that those state and federal duties are in fact different. Petitioner reasons that it *did* disclose the "intended use" of the device at issue—which petitioner appears to equate with whatever use is stated in the device's labeling (Pet. 27)—and that any liability must therefore rest on a violation of a further duty under state law to disclose any foreseeable off-label uses and any plans to market the device for those uses. See *ibid.*; Pharmaceutical Research and Manufacturers of America (PhRMA) Br. at 10-11.

That argument is unavailing, at least at this stage of the litigation. As the court of appeals recognized (Pet. App. 23a-24a), respondents' theory of liability does not appear to be that petitioner and its clients obtained a Section 510(k) clearance for one bona fide intended use while failing to disclose a foreseeable off-label use. Nor, in the claim at issue here, do respondents seek to hold petitioner liable for giving a physi-

cian information about an off-label use that was not identified in the Section 510(k) submission. See *id.* at 24a n.7; cf. *In re Orthopedic Bone Screw Prods. Liability Litigation*, 193 F.3d 781, 787 (3d Cir. 1999). Instead, respondents claim that AcroMed's bone plates and screws were never meant to be used at all for the intended use set forth in the Section 510(k) submissions; instead, respondents contend, the ostensible intended use was merely a pretext to get the device on the market, where it would be used exclusively for other (uncleared) uses. See Pet. App. 23a-24a; C.A. App. A57, A58.

Under the FDA's regulations, the "intended use" of a medical device is defined by the "objective intent of the persons legally responsible for the labeling of [the] device[]." 21 C.F.R. 801.4. That objective intent may be determined by (for example) labeling claims, advertising materials, written or oral statements, or the circumstances in which the device is offered and used. *Ibid.*; see also 21 C.F.R. 801.5. The complaints in this case allege that the devices at issue were meant solely for use in the spine, and that petitioner's representation to the FDA that the devices were intended for use in long bones was therefore false and misleading. C.A. App. A57, A58. Because that factual allegation has not been fleshed out in proceedings in the various district courts, it is impossible on the present record to say that any duty under state law would be "different from, or in addition to," applicable duties under federal law.[5]

[5] See 18 U.S.C. 1001 (1994 & Supp. IV 1998) (prohibiting false or fraudulent statements on any matter within the jurisdiction of a federal agency); 21 C.F.R. 807.87(k) (promulgated in 1992, see 57 Fed. Reg. 18,062, 18,064, 18,066 (1992)) (requiring each person submitting premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted"); 21 C.F.R. 807.87(h) (1985) (requiring, during the period relevant here, that parties submitting premarket notification must provide the FDA with "[a]ny additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution").

That is *not* to say that any representation to the FDA about a device's intended use must disclose every foreseeable use of the device. Physicians often employ medical devices for uses that are not identified in the labeling, and manufacturers may seek Section 510(k) clearance for the use identified in the labeling without setting forth every possible off-label use to which the device might be put after it reaches the market. But, for obvious reasons, the intended use stated in the premarket notification must be a bona fide use of the device; it cannot be a mere pretext calculated to clear the device for distribution exclusively for other uses.[6]

b. The present record also provides little support for petitioner's alternative contention (Pet. 27-29) that respondents' claim would "conflict" with the FDA's 1998 decision to classify and reclassify pedicle screw spinal systems for certain uses as Class II devices.[7] The FDA's classification and

[6] It is inaccurate to suggest, as petitioner does (Pet. 27; see also PhRMA Br. 10-11 & n.6), that the FDA never inquires, and lacks authority to inquire, into off-label uses in connection with premarket notification submissions under Section 510(k). Although 1997 amendments to the FDCA confine FDA's determination of the intended use of a device, for purposes of a Section 510(k) clearance, to its proposed labeling, see 21 U.S.C. 360c(i)(1)(E)(i) (Supp. IV 1998), the FDA may nonetheless "require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling" if the FDA determines "that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device," and "that such use could cause harm." 21 U.S.C. 360c(i)(1)(E)(i)(I)-(II) (Supp. IV 1998). FDA recently explained that, "[w]hile this is a new statutory requirement, it is important to note that it is not different from the manner in which 510(k)s have traditionally been reviewed." Office of Device Evaluation, Center for Devices and Radiological Health, FDA, *Determination of Intended Use for 510(k) Devices—Guidance for Industry and CDRH Staff* 1 (Jan. 30, 1998).

[7] Tort claims may be subject to conflict preemption under the MDA even if they are not expressly preempted under Section 360k. See *Medtronic*, 518 U.S. at 502-503; *id.* at 507-508 (opinion of Breyer, J.).

reclassification decision—which occurred long after the underlying events at issue here (see Pet. App. 5a)—was based on "new information," including studies conducted years after petitioner obtained Section 510(k) clearance for AcroMed's devices. See 63 Fed. Reg. at 40,025-40,026. That decision operates prospectively and does not legitimize conduct that was previously impermissible. *Id.* at 40,037-40,038. Moreover, the FDA classified and reclassified pedicle screw spinal systems as Class II devices only for certain spinal uses, and it imposed four "special controls" requiring that the devices' labeling contain a special warning and that they comply with material standards, mechanical testing standards of performance, and biocompatibility standards. See *id.* at 40,027, 40,034-40,038. The sample complaint relied on by the court of appeals does not indicate whether AcroMed's devices were marketed for the uses for which the devices are now classified as Class II or whether their manufacture and composition were consistent with the special controls that the FDA has now prescribed. See Pet. App. 8a-9a; C.A. App. A42-A131. For these reasons, petitioner has not established that a tort judgment for respondents would contradict the FDA's 1998 determination; and, in any event, the allegedly tortious actions occurred before that determination.

c. Nevertheless, in our view, federal supremacy principles do preclude respondents' "fraud on the FDA" claim.

Respondents' claim is quite peculiar. It is independent of any claim against the manufacturer of the device in question, and it apparently does not depend on any showing that the device was somehow defective, or falsely advertised, under state law. See Pet. App. 8a-9a. Instead, respondents simply contend that, but for petitioner's alleged misrepresentations to the FDA, the agency would not have cleared the device for marketing, the device would not have been marketed, and it therefore would not have harmed respondents. *Ibid.* The focus of the claim is therefore not on the device itself or on any provisions of state law that might apply directly to

the device or to its manufacturing and distribution, but rather solely on the character of the relationship between petitioner and the federal government. Absent a contrary direction by Congress, that relationship is, as a general matter, governed by federal not state law.

In the typical preemption context, when Congress legislates "in a field which the States have traditionally occupied," preemption analysis begins "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485 (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The common law duties at issue in *Medtronic*, concerning the manufacture and distribution of a device that was allegedly defective under state law, fell squarely within such a field. By contrast, the field of relationships between the federal government and persons who are subject to regulation by it—and, more particularly, the field of submissions made by such persons to a federal agency—is not one "which the States have traditionally occupied." *Ibid.* Like issues concerning the relationship of the United States with its contractors and employees, the duties of persons in connection with their submission of applications to a federal agency for benefits or regulatory approval involve "uniquely federal interests" that "warran[t] the displacement of state law." See *Boyle* v. *United Techs. Corp.*, 487 U.S. 500, 504-505 (1988). Those "uniquely federal interests" remain predominant when questions concerning that relationship are raised, as here, in private civil litigation. Compare *id.* at 506-507. Thus, duties concerning the submission of information to a federal agency are, at least as a general matter, appropriately defined and enforced by the federal government. See also *Pennsylvania* v. *Nelson*, 350 U.S. 497, 505 (1956) (state laws criminalizing sedition against the United States, the subject of federal legislation, are preempted because sedition is "not a *local* offense," but is a "crime against the

Nation," and thus "prosecutions should be exclusively within the control of the Federal Government") (internal quotations omitted). Cf. *Hancock* v. *Train*, 426 U.S. 167, 178-179 (1976); *Mayo* v. *United States*, 319 U.S. 441, 445-446 (1943).

There is no occasion in this case to decide, however, whether federal law completely occupies the field of submissions made by or on behalf of regulated parties to a federal agency, either generally or specifically with respect to the FDA. That is so because the premise of respondents' state-law cause of action is that particular agency action should not and would not have been taken by a federal agency, and that damages should be awarded as if the conduct of petitioner that the FDA had *cleared* under the FDCA—introducing the product onto the market—was *unlawful* under the FDCA. A state court may not decline to give effect to an FDA decision that has not been rescinded by the FDA or set aside by a court. Cf. *Nantahala Power & Light Co.* v. *Thornburg*, 476 U.S. 953 (1986); *Chicago & North Western Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). The federal government has a significant interest in the finality of its own administrative determinations, and under the Supremacy Clause those determinations should generally be questioned or set aside, if at all, only by the federal government itself. See, *e.g.*, *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1505 (11th Cir. 1997), cert. dismissed, 523 U.S. 1123 (1998).

A contrary rule could produce undesirable practical consequences. In the absence of an applicable privilege, see generally *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 150-151 (1975), "fraud on the agency" claims could subject federal agencies to countless, highly intrusive inquiries into their internal deliberations. For example, respondents assert, as necessary elements of liability, that the FDA "was ignorant" of the true intended use of the device in question; that the FDA "reli[ed]" on petitioner's misrepresentation about that intended use; and that the FDA "would not have issued

§ 510(k) clearances" for the device in the absence of petitioner's alleged fraud. Pet. App. 8a-9a.

In litigating those issues, the parties would undoubtedly seek discovery from the FDA concerning agency officials' states of mind and the hypothetical courses of action that agency decisionmakers might have taken under various counterfactual scenarios. It is the position of the United States that its employees are immune from third-party subpoenas issued in private litigation, that testimony must be sought under an agency's *Touhy* regulations, see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951), and that an agency's denial of a request for testimony by agency employees is subject to review only under the "arbitrary and capricious" standard of the Administrative Procedure Act, 5 U.S.C. 706(2)(A). The lower federal courts have, however, taken divergent views on that question. Compare, *e.g.*, *Comsat Corp.* v. *National Science Found.*, 190 F.3d 269, 277-278 (4th Cir. 1999) (applying APA standard), with *Exxon Shipping Co.* v. *United States Dep't of the Interior*, 34 F.3d 774, 778-780 (9th Cir. 1994) (agency must produce evidence in response to subpoena, subject only to court's discretion to limit discovery under Fed. R. Civ. P. 26 and 45). And, in any event, widespread litigation could be expected on whether testimony and other evidence could be secured from the FDA and other federal regulatory agencies in cases such as this; this multidistrict litigation alone involves thousands of plaintiffs in more than 2000 cases that could be tried in several dozen different judicial districts. The prospect of such intrusive inquiries and attendant litigation would pose a significant potential for diverting an agency's resources and for distorting its internal decisionmaking processes.[8]

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[8] We have pointed to similar concerns in suggesting, in response to the Court's invitation in *Armstrong Surgical Ctr.* v. *Armstrong Cty. Mem. Hosp.* (No. 99-905), that there is reason for caution in fashioning any

Permitting state law suits for fraud on a federal agency could also distort the behavior of regulated entities. If a regulated entity knows that a jury applying the tort law of one of 50 States will play a central role in interpreting the entity's duties to the federal government, that concern would cause it to alter its behavior in unpredictable ways that may well be inconsistent with the efficient administration of the federal regulatory scheme.

2. The petition for certiorari should be granted. As the court of appeals acknowledged (Pet. App. 17a n.5), its decision squarely conflicts with *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (*Mitchell II*), cert. denied, 523 U.S. 1020 (1998), in which the Seventh Circuit held that, despite *Medtronic*, the MDA preempts claims of "fraud through * * * representations to the FDA during the PMA process." *Id.* at 914; see also *Lewis*, 107 F.3d at 1505 (finding analogous fraud-on-the-agency claim preempted under Boat Safety Act). We agree with petitioner (see Reply Br. 3-4) that the Seventh Circuit would be bound to follow that precedent today, even though the abbreviated analysis in *Mitchell II* placed some reliance on a prior Third Circuit decision overruled by the decision below. We also agree with petitioner (see Reply Br. 4 n.2) that the decision below squarely conflicts with *Mitchell II* even though the latter

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theory of federal antitrust liability that would allow a plaintiff to recover damages from a private defendant for competitive injuries most directly caused by state administrative or adjudicatory action. 99-905 U.S. Br. at 16-18. At the same time, however, other circumstances counsel caution in concluding that claims like that in *Armstrong* may *never* be meritorious: antitrust claims are made within a well-developed legal framework, and are based on a federal statute that specifically prohibits concerted private conduct in restraint of trade, quite apart from any involvement by government actors. Those circumstances are not present in this case. Furthermore, antitrust cases, unlike this case, raise no question under the Supremacy Clause; and, unlike in this case, any conflict in the circuits on the question presented in *Armstrong* is not current or well-defined enough to require immediate review. See 99-905 U.S. Br. at 14-16, 20.

decision involved the PMA process and this case involves the Section 510(k) process. Finally, we agree that the subject-matter of the conflict is sufficiently important to warrant this Court's review; if other courts were to follow the Third Circuit's lead and permit state-law suits in this context, the result could be an unwelcome proliferation of similar claims asserting fraud on a variety of federal agencies.

To be sure, this particlar case arrives here in an interlocutory posture. The court of appeals remanded respondents' individual claims for trial, at which it would be determined, among other things, whether "the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on [petitioner] in the circumstances alleged." Pet. App. 25a. Because the court of appeals "d[id] not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted" (*id.* at 24a-25a), it is theoretically possible that, on remand, petitioner could prevail in every case on state law grounds. Nonetheless, the court of appeals concluded (*id.* at 19a-24a) that respondents' claims against petitioner have a plausible basis in common law tort principles, and we agree with respondents (Br. in Opp. 10 n.6) that those claims might well be cognizable under the law of at least some States.[9] In our

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[9] See, *e.g.*, *Learjet Corp.* v. *Spenlinhauer*, 901 F.2d 198, 201 (1st Cir. 1990) ("[i]f, as [plaintiff] alleges, the [Federal Aviation Administration] relied on Learjet's fraudulent misrepresentations when it certified the [airplane model], and [plaintiff] purchased the [airplane] in reliance on the FAA's certification, then he has indirectly relied on Learjet's fraudulent misrepresentations" and has stated a cause of action under Kansas law); *Stanton by Brooks* v. *Astra Pharm. Prods., Inc.*, 718 F.2d 553, 569 (3d Cir. 1983) (recognizing state-law cause of action for negligent failure to file certain reports with the FDA, where, but for that negligence, the FDA "would have required notice to the medical community" of certain drug risks and "physicians receiving this information would have considered it" in deciding whether and how to administer the drug); *Hawkins* v. *Upjohn Co.*, 890 F. Supp. 609, 612 (E.D. Tex. 1994) (recognizing state-law cause of action for fraud where "[p]laintiffs assert that the FDA relied on defendants' representations in permitting the distribution of the drugs in

view, this Court therefore should grant certiorari now to decide whether such claims are foreclosed by federal law, rather than after years of what is very likely to be burdensome litigation under this and other federal statutory schemes—including numerous individual cases in numerous district courts with respect to pedicle screws alone.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted.

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question * * * and that plaintiffs[] relied on the FDA's assessment as to the drugs' safety in choosing to use the drugs"); see also *Connelly* v. *Iolab Corp.*, 927 S.W.2d 843, 855 (Mo. 1996), cert. dismissed, 520 U.S. 1260 (1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 n.7 (Pa. 1996), cert. denied, 520 U.S. 1168, 1212 (1997). But cf. *Sebago, Inc.* v. *Beazer East, Inc.*, 18 F. Supp. 2d 70, 86-88 (D. Mass 1998).